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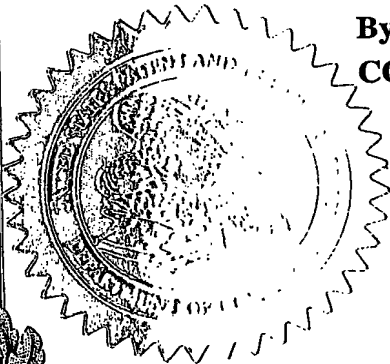
November 10, 2004

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Use a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53 (c).

Docket Number		4398-312	Type a plus sign (+) inside this box →	+
INVENTOR(S)/APPLICANT(S)				
LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)	
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TITLE OF THE INVENTION (280 characters)

VENT SYSTEM FOR CPAP PATIENT INTERFACE USED IN TREATMENT OF SLEEP DISORDERED BREATHING

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ENCLOSED APPLICATION PARTS (check all that apply)



Specification

Number of Pages

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Applicant claims "small entity" status.



Drawing(s)

Number of Sheets

27



"Small entity" statement attached.



Other (specify)

METHOD OF PAYMENT (check one)



A check or money order is enclosed to cover the Provisional filing fees (\$160.00)/(\$80.00)



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Respectfully submitted,
SIGNATURE

DATE

November 25, 2003

TYPED or PRINTED NAME

Paul T. Bowen

REGISTRATION NO.
(if appropriate)

38,009



Additional inventors are being named on separately numbered sheets attached hereto.

PROVISIONAL APPLICATION FILING ONLY

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U.S. PATENT APPLICATION

Inventor(s): Donald Darkin
Patrick John McAuliffe

Invention: VENT SYSTEM FOR CPAP PATIENT INTERFACE USED IN
TREATMENT OF SLEEP DISORDERED BREATHING

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SPECIFICATION

VENT SYSTEM FOR CPAP PATIENT INTERFACE USED IN TREATMENT OF SLEEP DISORDERED BREATHING

FIELD OF THE INVENTION

[001] The invention relates to a vent system for use with a Continuous Positive Airway Pressure (CPAP) patient interface, e.g. a mask, used in treatment of Sleep Disordered Breathing.

BACKGROUND

[002] The use of nasal CPAP apparatus to treat "snoring sickness" was pioneered by Sullivan and taught in US Patent 4,944,310. Nasal CPAP apparatus typically comprises a blower, an air delivery conduit and a patient interface. The blower provides a supply of air or breathable gas at positive pressure. The conduit interconnects the blower and the patient interface. A variety of nasal masks, nose & mouth masks, full face masks, nasal prongs and nasal pillows are used to provide an interface with the patient.

[003] A typical mask comprises:

(i) a rigid or semi-rigid portion, termed a shell or frame, which defines a nose-receiving cavity; &

(ii) a soft patient contacting portion, termed a cushion or membrane.

Cushions have been constructed from silicone, foam, gel and combinations of these materials.

[004] Since a patient typically exhales into the same mask cavity wherefrom they inhale, the possibility of rebreathing of carbon dioxide (CO₂) exists. In conjunction with a sufficient continuous flow of fresh air or breathable gas, a vent can allow a controlled leak from the mask cavity and hence provide for the washout of CO₂. Unfortunately, the noise of air or breathable gas from the vent can disrupt anyone within earshot attempting to sleep. Hence there is an advantage in providing a low-noise vent.

[005] One form of known vent is described in US Patents 6,561,190 (Kwok) and 6,561,191 (Kwok). These patents describe the use of grommet in a mask frame. The contents of these

patents are hereby incorporated by cross-reference. A vent in accordance with embodiments of these inventions is found in the MIRAGE™ mask, manufactured by ResMed Limited.

[006] Another known form of vent is described in International Patent Application PCT/AU00/00636 (Drew et al.) published as WO 00/78381. This patent application describes the use of a connector for a mask having a vent along a smooth continuing surface. The contents of this patent application are hereby incorporated by cross-reference. A vent in accordance with an embodiment of this invention is found in the ULTRA MIRAGE™ mask, manufactured by ResMed Limited.

[007] Another known form of vent is described in US Patent 6,581,594 (Drew et al.). This patent describes the use of a vent which, in one form, comprises a thin air permeable membrane. The contents of this patent application are hereby incorporated by cross-reference.

[008] Another known form of vent is described in International Patent Application PCT/AU01/01658 (Dantanarayana et al.) published as WO 02/051486. This patent application describes the use of a flow regulation vent. The contents of this patent application are hereby incorporated by cross-reference.

[009] US Patent 6,557,555 (Hollis) describes a vent valve apparatus. The contents of this patent application are hereby incorporated by cross-reference.

[010] Another known vent is the Respironics WHISPER swivel.

[011] European Patent No. 0 697 225 discloses a vent formed from a porous sintered material.

[012] A known vent, manufactured by Gottlieb Weinmann Geräte Für Medizin Und Arbeitsschutz GmbH and Co. comprises a generally cylindrical insert to be interposed in use, between the mask shell and the gas conduit. The insert includes a window which is covered with a porous sintered material of approximately 3-4 mm thickness.

[013] Another type of vent intended to be inserted between the mask shell and the breathable gas supply conduit is the E-Vent N by Draeger medizintechnik GmbH (the Draeger vent). The Draeger vent comprises a stack of 21 annular disks, which have slots in their adjacent surfaces for gas to flow therethrough. Each slot has a length of 5 to 7 mm as measured along the path from the interior of the vent to atmosphere.

[014] Typically vents are designed with sufficient porosity to provide enough vent flow at a low pressure (e.g. 4 cmH₂O) to ensure adequate washout of CO₂.

[015] Reducing the pore size of a vent can make the vent quieter, but can also increase the chances that the vent will clog.

[016] Problems with prior art vents include that they can be too noisy, that they clog with dirt and moisture (particularly when used with humidifiers), that they are awkward or difficult to clean or assemble and that they have designs which are sensitive to very small changes in the manufacturing process which can lead to variation in the pressure flow relationship.

SUMMARY OF THE INVENTION

[017] In accordance with a first aspect of the invention there is provided a vent for a CPAP patient interface.

[018] In accordance with a second aspect of the invention there is provided a vent assembly comprising at least two alternative vents each having substantially the same pressure-flow characteristics.

[019] In accordance with a third aspect of the invention there is provided a vent assembly comprising at least two alternative vents each having different pressure-flow characteristics.

[020] In accordance with another aspect of the invention there is provided a vent assembly comprising at least two alternative vents and a mount adapted to support at least one vent in a venting position.

[021] In accordance with another aspect of the invention there is provided a vent assembly comprising at least two alternative vents and a mount adapted to support at least one vent in a venting position and a locking mechanism adapted to retain said at least one vent in a venting position.

BRIEF DESCRIPTION OF THE DRAWINGS

- [022] Fig. 1 shows a schematic diagram of a prior art blower, air delivery conduit and patient interface.
- [023] Fig. 2 shows a related art mask with swivel elbow.
- [024] Fig. 3 shows a cross-section of a related art patient interface in position on a patient's face with swivel elbow.
- [025] Fig. 4a-c show side views, a cross section and a detail of a swivel in accordance with a first embodiment of the invention.
- [026] Fig. 5a-c shows a swivel in accordance with a first embodiment of the invention in three positions.
- [027] Fig. 6 shows an exploded perspective view of a swivel elbow in accordance with a second embodiment of the invention.
- [028] Fig. 7 shows a swivel elbow assembly in accordance with a second embodiment of the invention with the vent in a "coarse" hole position.
- [029] Fig. 8 shows a swivel elbow assembly in accordance with a second embodiment of the invention with the vent in a "fine" hole position.
- [030] Fig. 9 shows a swivel elbow sleeve in accordance with a second embodiment of the invention.
- [031] Fig. 10 shows a swivel elbow assembly in accordance with another embodiment of the invention, suitable for use with a RESMED ULTRA MIRAGE mask.
- [032] Figs. 11a and 11b show a sliding vent assembly in accordance with an embodiment of the invention.
- [033] Fig. 12 shows a further view of the vent assembly of Fig. 11a.
- [034] Fig. 13 shows a drawing of the vent assembly of Fig. 11a.
- [035] Fig. 14 shows an alternative view of the vent assembly of Fig. 11a.
- [036] Fig. 15 shows a front view of a swivel elbow with vent assembly in accordance with a first embodiment of the invention.
- [037] Fig. 16 shows a side view of a swivel elbow with vent assembly in accordance with a first embodiment of the invention.
- [038] Fig. 17 shows a front view of an assembly including mask frame and swivel elbow with vent assembly in accordance with a first embodiment of the invention.

[039] Fig. 18 shows a side view of the assembly of Fig. 17.

[040] Fig. 19 shows a perspective view of the assembly of Fig. 17.

[041] Fig. 20 shows an embodiment of the invention which incorporates visual, tactile and aural feedback of vent position.

[042] Fig. 21 shows an embodiment of the invention which incorporates an electrical resistance sensor.

[043] Fig. 22 shows an embodiment of the invention with a slidable vent cover exposing a set of larger holes.

[044] Fig. 23 shows an embodiment of the invention with a slidable vent cover exposing a set of smaller holes.

[045] Fig. 24 shows an embodiment of the invention with a hinged vent cover.

[046] Figs 25a and 25b show an alternative embodiment of the invention incorporating a rotating vent cover.

[047] Fig. 26 shows a cartridge-style embodiment of the invention in exploded view.

[048] Figs 27a and 27b show the cartridge-style embodiment of the invention in two different positions.

DESCRIPTION OF THE INVENTION

[049] Fig. 1 shows a blower 10 connected to an air delivery conduit 20 and the air delivery conduit 20 connected to a patient interface 30. In the view shown in Fig. 1, the patient interface 30 is a nasal mask. The patient interface 30 includes a vent 40. The vent 40 includes six holes 50.

[050] Fig. 2 shows an alternative nasal mask, the MIRAGE® ACTIVA™ nasal mask. This mask includes a swivel elbow 60. The swivel elbow is described in further detail in the Applicant's co-pending International Patent Application PCT/AU03/01162, the contents of which are hereby incorporated by cross-reference. The swivel elbow 60 includes a vent cover 70 having a number of holes 50 therethrough.

[051] Fig. 3 shows a cross-section of a patient interface 30 in position on a face of a patient 80. A swivel elbow 60 is shown detached and in front of the patient interface 30. The cavity 90 into which the patient 80 can exhale nasally can accumulate carbon dioxide unless it is washed out through the vent 40 included in the elbow 60.

[052] In a first embodiment of the invention, a vent assembly is provided with two alternative vents, vent *a* and vent *b* as shown in Fig. 4-5. Both vent *a* and vent *b* provide approximately the same total flow. Vent *a* provides relatively fewer large vent holes, whereas vent *b* provides a matrix of relatively smaller holes (e.g. below 0.5mm diameter, preferably approximately 0.1mm in diameter). Selection between vent *a* and vent *b* is made by rotating or sliding a cover so that either the small or large holes are lined up with an orifice on a mating surface.

[053] As shown in Fig. 4a and 4b in exploded views, a vent assembly 90 in accordance with an embodiment of the invention comprises a generally cylindrical first portion 100 and a generally cylindrical sleeve portion 110. The first portion 100 includes an orifice or window 102. The sleeve portion 110 includes, in one embodiment, two alternative sets of holes corresponding to vents *a* and *b* respectively. Vent *a* uses three large holes. Vent *b* uses a series of smaller holes. In use the sleeve portion 110 rotatably fits over an end of the first portion 100. In the embodiment of the invention shown in Fig. 4a, the sleeve is free to rotate

through 180° degrees as shown by the arrows in Fig. 5a-5c, although in other embodiments the sleeve may rotate through fewer degrees. As shown in Fig. 4a-4b, both the first portion 100 and sleeve portion 110 are hollow which allows air to pass between the interior of the first portion 100 through window 102 and thence through either of vent holes *a* or *b*. Fig. 4c shows a detail of the vent with small holes.

[054] In a second embodiment of the invention the vent assembly is formed as part of a swivel elbow 120, for example, the swivel elbow used on the MIRAGE® VISTA™ mask, manufactured by ResMed Limited, as shown in Fig. 6-9. The elbow 120 includes a shaft 130 with an orifice 132 therein. The shaft 130 includes an alignment tab 134. A sleeve 140 includes a pair of alternative vents 142, 144 and a pair of slots 146, 148, each one associated with one vent, each adapted to receive the alignment tab of the shaft. In use, the orifice 132 of the shaft 130 aligns with either vent 142 or vent 144. In order to change from one vent to another, the vent assembly is pulled apart, rotated 180°, and re-assembled. In this way, at least one of and only one of vents 142 or 144 is used at one time.

[055] In a third embodiment of the invention the vent assembly includes a moving part. The moving part can be located in each of two positions by having a protrusion on one part match a depression on the matching part. When the vent assembly is partway between the two vent positions, the protrusion can act to separate the matching parts so that the vented airflow is greater than in either of the two correct positions. This provides a fail-safe mechanism where an incorrect position results in high airflow (a safe condition) and also higher noise (warning the user of the mistake).

[056] A typical vent comprises a number of vent holes. For example, three vent holes with a diameter of 2.7mm. The effective area of a vent hole is generally smaller than the actual cross-sectional area of the vent hole. Small holes have a relatively smaller effective area than large holes, e.g. about 10% smaller. The effective area of a vent is the sum of effective areas of its constituent vent holes. In one form the alternative vents have the same effective areas.

[057] In another embodiment of the invention, alternative vent constructions are used instead of using holes. For example, vent *a* and vent *b* are laminar flow elements, such as used in the

ULTRA MIRAGE® mask. In another form sintered materials are used to construct the vent. In another form, vents are constructed from foam polymers. Combinations of different vents may be used, for example, a vent with holes and a vent constructed from a sintered material. The assembly may comprise more than two vents, for example a vent with holes, a sintered vent and a laminar flow element-type vent.

[058] In some cases, such as clinical studies, it is desirable to test the effectiveness of a particular treatment regime, or mask and compare it with a suitable control. For example, it might be desired to test the effectiveness of an algorithm for providing nasal CPAP therapy. In such a situation, it would be desirable to be able to discount the effect of wearing the mask per se. This could be achieved by using a "sham" mask, for example, a mask with a very large vent hole. An example of a sham mask is taught in published PCT patent application WO 02/066,105. A difficulty of using a dedicated "sham" mask is that the patient may be aware that they are using the sham mask, or that it may be necessary to disturb their sleep in order to don such a sham mask.

[059] The vent assembly may include a sham vent as an alternative. Such a sham vent would have a very high permeability, e.g. a large hole. By use of the invention, it would be possible for a clinician to switch from a "treatment" vent to a "sham" vent, with minimal disturbance to a sleeping patient and thus obtain clearer results for a clinical study.

[060] Whilst in a preferred form the different vents are alternatives, in one form more than one vent may be used at once, for example, 1/2 vent *a* and 1/2 vent *b*.

[061] In a vent comprising vent holes, increasing or decreasing the number of holes in the vent allows the vent flow to be set to any desired level. In this way a vent assembly in accordance with the invention can be designed to have pressure flow characteristics that mimic prior art masks which use vents with holes.

[062] A variety of materials may be used to construct the vent assembly, for example, polycarbonate (e.g. MAKROLON), or other polymers, stainless steel, sintered ceramic or

PTFE, and foam polymers. It may be particularly advantageous to use hydrophobic materials such as PTFE for small pored vents to reduce clogging of pores.

[063] In an alternative form, instead of being mounted on a swivel elbow, a vent assembly 200 in accordance with an embodiment of the invention is mounted on or formed as part of a patient interface frame 210. Fig. 11-14 show a frame for a patient interface which comprises two generally cylindrical end portions 220 interconnected by a generally rectangular backbone 230. A clip 240 is slidably positioned on the backbone 230. The clip 240 includes at least two alternative vents 250, 260. An orifice or window in the backbone 230, similar to orifice or window 102, provides for fluid communication to an interior of the patient interface. By sliding the clip 240 to alternatively align vent 250 or 260 with the orifice 230, exhaled air can be vented via vent 250 or 260. Fig. 11a shows the clip 240 in a first position, and Fig. 11b shows the clip 240 in a second position.

[064] Fig. 22 and 23 show an alternative embodiment of the invention in a nasal mask 300. This form of the invention includes a slidable vent cover 310 which in a first position 305 exposes a set of large vent holes 320 and in a second position 315 exposes a set of small vent holes 330. In one form the large and small vent holes are molded into a silicone grommet 325 which is removeably insertable into a mask frame, in a similar manner to US Patents 6,561,190 and 6,561,191 (Kwok). When holes are exposed the passage of air between the interior of the mask and the exterior of the mask can occur therethrough.

[065] Fig. 24 shows an alternative form of the invention in a nasal mask 400. This form of the invention includes a hinged vent cover 410. In the form shown in Fig. 24, the vent cover is generally rectangular and one side is hinged. Similarly to the vent assembly shown in Fig. 22 and 23, the holes of Fig. 24 may be moulded into a removeably insertable grommet 425. The vent cover 410 can alternatively block the set of small vent holes 430 and the set of large vent holes 420.

[066] Fig. 25a and 25b show an embodiment of the invention 500 incorporating a rotating vent cover 510 in a first and second position respectively on a vent elbow. The vent cover 510 is generally disc shaped having a window 525 therethrough. By rotating the vent cover 510

through, for example 120° different sets of holes are exposed. In the view shown in Fig. 25a, a set of large holes 520 are exposed. In the view shown in Fig. 25b a set of small holes 530 are exposed. Each respective set of holes 520, 530 provides a conduit communicating with an interior of the mask. In an alternative form (not shown) the rotateable vent cover includes different sets of holes and there is a fixed position window to which the vent cover is attached. Rotating the vent cover presents a different set of vent holes to the window resulting in a different vent characteristic.

[067] Fig. 26, 27a and 27b show an alternative form of the invention including a replaceable vent cartridge. In this form of the invention the vent assembly comprises a shaft 600, a rotateable sleeve 620 including a window 625 and a replaceable cartridge 630 with holes therethrough. The vent assembly is shown in exploded view in Fig. 26. When assembled, the cartridge 630 is slid into position over the shaft 600 and under the sleeve 620. In the form shown in Fig. 27a-27b, in use the cartridge 630 is designed to be not rotateable about a longitudinal axis of the shaft 600. In contrast, the sleeve 620 is designed to be so rotateable exposing a different set of holes in the cartridge 630 as shown in Fig. 27a and 27b. In use the holes of the cartridge 630 provide for fluid communication from the interior of the shaft 600 to atmosphere. Because small vent holes can become clogged with use, the sleeve 620 can be rotated after a suitable period (e.g. overnight). One cartridge might thus provide each night a clean set of vent holes for a week without requiring cleaning. At the end of the week, the cartridge may be disposed of a replaced with a clean one.

[068] Advantages of the invention include:

When in the quiet position (fine holes) the mask will be extremely quiet, and with no discernable air jets. This makes the mask far less disturbing to both the wearer and any bed partner.

[069] When in the normal (large holes) position, the mask will be suitable for use with a humidifier which might clog smaller holes. When the humidifier is not needed, the vent assembly can be switched easily to the quiet, small hole vent.

[070] The use of a moveable part means that the patient does not need to keep spare parts and is precluded from losing components or not being able to fit them.

[071] Use of the invention enables masks to be compatible with a range of different flow generators or blowers. For example, a first flow generator or blower may be pre-programmed to operate assuming a first vent characteristic and a second blower, a second vent characteristic. Since the same mask can mimic different vent characteristics, the same mask can be used on both blowers once set to the appropriate vent.

[072] Another advantage of the invention is to provide different vents for different pressure ranges. For example, at low pressures, it may be appropriate to have a vent with large holes in order to provide sufficient vent flow. The same vent at higher pressures would have unnecessarily high vent flow which leads to increased noise. Hence in accordance with an embodiment of the invention, when a patient is using a generally low pressure treatment, they can utilise a first vent, but when treatment pressures are higher they can use a second vent.

[073] Another advantage of the invention is that it provides a quick and simple system of replacing disposable vents. For example, certain styles of vents may clog easily and be designed for a single night's use. In accordance with an embodiment of the invention a vent assembly can comprise a set of "single use" vents. After a first night's use, the patient can switch to the second vent. After a second night's use, the patient can switch to a third vent, and so on.

[074] In another form of the invention, sensors and/or indicators are included in the vent assembly as shown in Fig. 20 & 21. The vent assembly 300 includes a shaft 302 and a sleeve 304. The shaft 302 includes an orifice 306 which allows air to pass through. By rotating the sleeve 304 alternative vents 308 and 310 are aligned over the orifice 306. The sensor detects which of the vents is being used and conveys the information to a flow generator controller. In one form the sensor has a different electrical resistance, depending on the vent being used, as shown in Fig. 21 and discussed further below. Sensor information may be conducted to the flow generator controller via wires along the air delivery conduit, or wirelessly, for example via a BLUETOOTH™ compatible system. The flow generator controller receives the sensor

information and adjusts the parameters for the algorithms controlling therapy. Alternatively or additionally the vent assembly includes an indicator of vent position which may be visual, aural, tactile or some combination. As shown in Fig. 20, the vent assembly 300 includes an alignment arrow 312 moulded on the shaft 302. Each vent 308, 310 has an adjacent indicator (e.g. an arrow, dot or some other shape) 309, 311 molded onto the sleeve 304. The indicators may present a characteristic feel depending on the vent position so that they can be recognised in the dark. Additionally or alternatively, the vent assembly may exhibit a characteristic "click" as its vent is changed as shown in Fig. 20. The vent assembly may display a tag of different colour depending on the vent position.

[075] Fig. 21 shows schematic of a slidable cover 350 forming part of the vent assembly similar to Fig. 11-14. When the appropriate vent 352 or 354 is aligned over an orifice (not shown), a corresponding resistor 353 or 355 electrically connects to a connector 356 which is in electrical communication with a flow generator controller 358. Thus the flow generator controller 358 can detect which vent is being used and adjust pressure, flow or some other parameter of the blower as necessary.

[076] This ability to communicate the selected vent to the flow generator allows for the flow generator to provide an appropriate response. A response may be to make an adjustment to its control algorithm taking into account the characteristic of the recognized selected vent. In addition or alternatively the flow generator may not operate in treatment mode or only operate within a predetermined pressure range when the user attempts to commence treatment having selected the less than optimum vent or the characteristics of the selected vent is not recognized by the flow generator.

[077] In addition or alternatively the flow generator may prompt the selection of the optimum vent for a given control algorithm or air circuit configuration. Having detected the selection of a vent the flow generator may present a messages to the user. The message may be by way of an auditory or visual alarm. Through use of the flow generator status display (typically an alpha-numeric LCD panel) the flow generator may present a statement as to the detected vent condition and either confirm its appropriateness or suggest corrective action.

[078] As the invention allows for a selection to be made between vents the flow generator may communicate to the user that a selected vent is satisfactory or unsatisfactory depending on the treatment pressure range it is set to deliver. For a higher pressure range the flow generator may prompt the use of a small hole vent while suggesting a larger hole vent where it is to operate in the lower pressure range.

[079] If the flow generator can detect a deterioration of vent performance over time (for example due to the vent becoming blocked during one treatment session or over a number of sessions) then a prompt may be given for the selection of an alternative vent.

[080] Such a system is of use where available air circuit configurations may include a humidifier. If the flow generator detects that a small hole (e.g. mesh vent) is selected while the air circuit is set up to operate with a humidifier the flow generator may send a message to the user in order to prompt the selection of a more suitable vent.

[081] Although the invention has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.

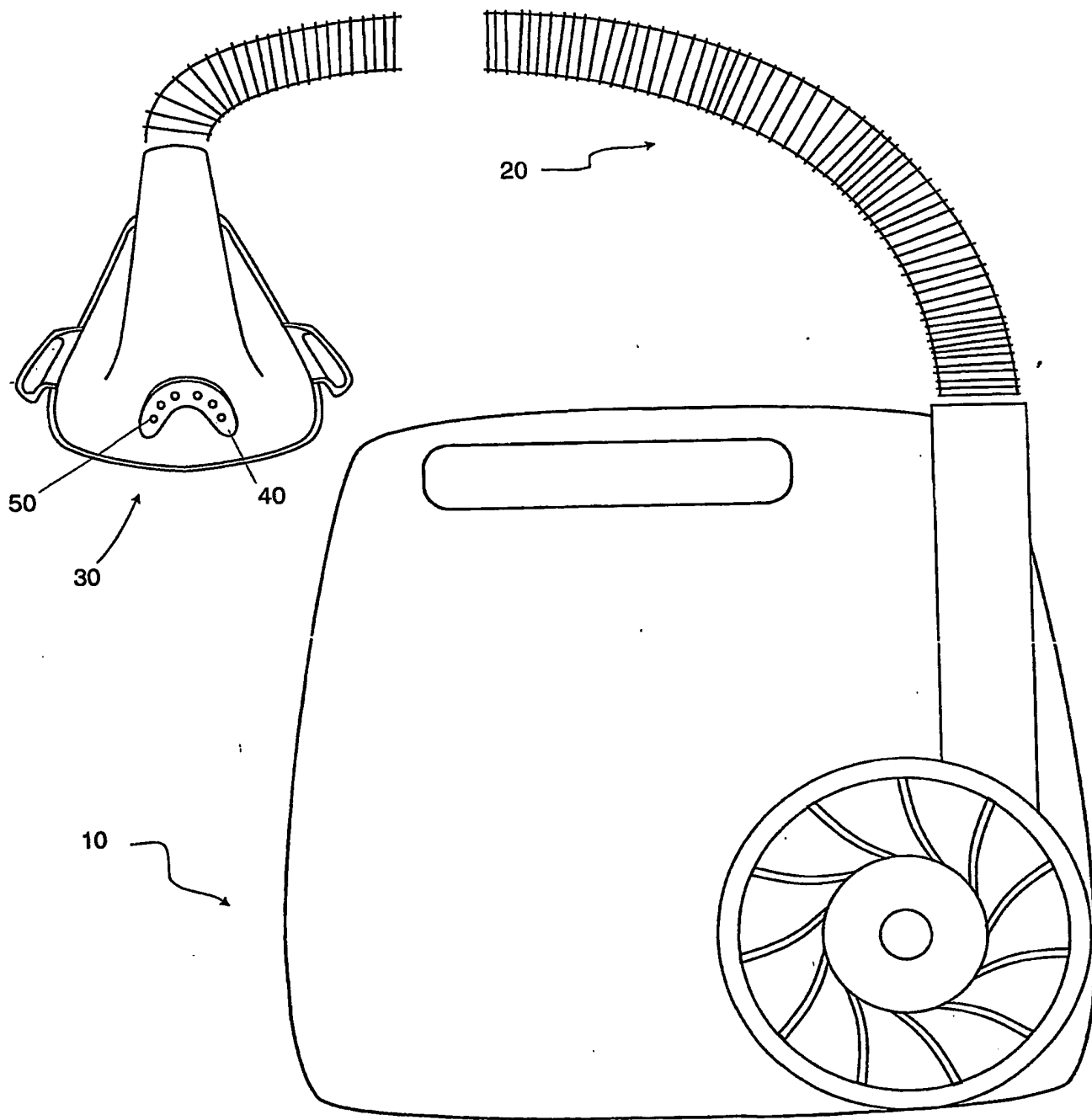


Fig. 1

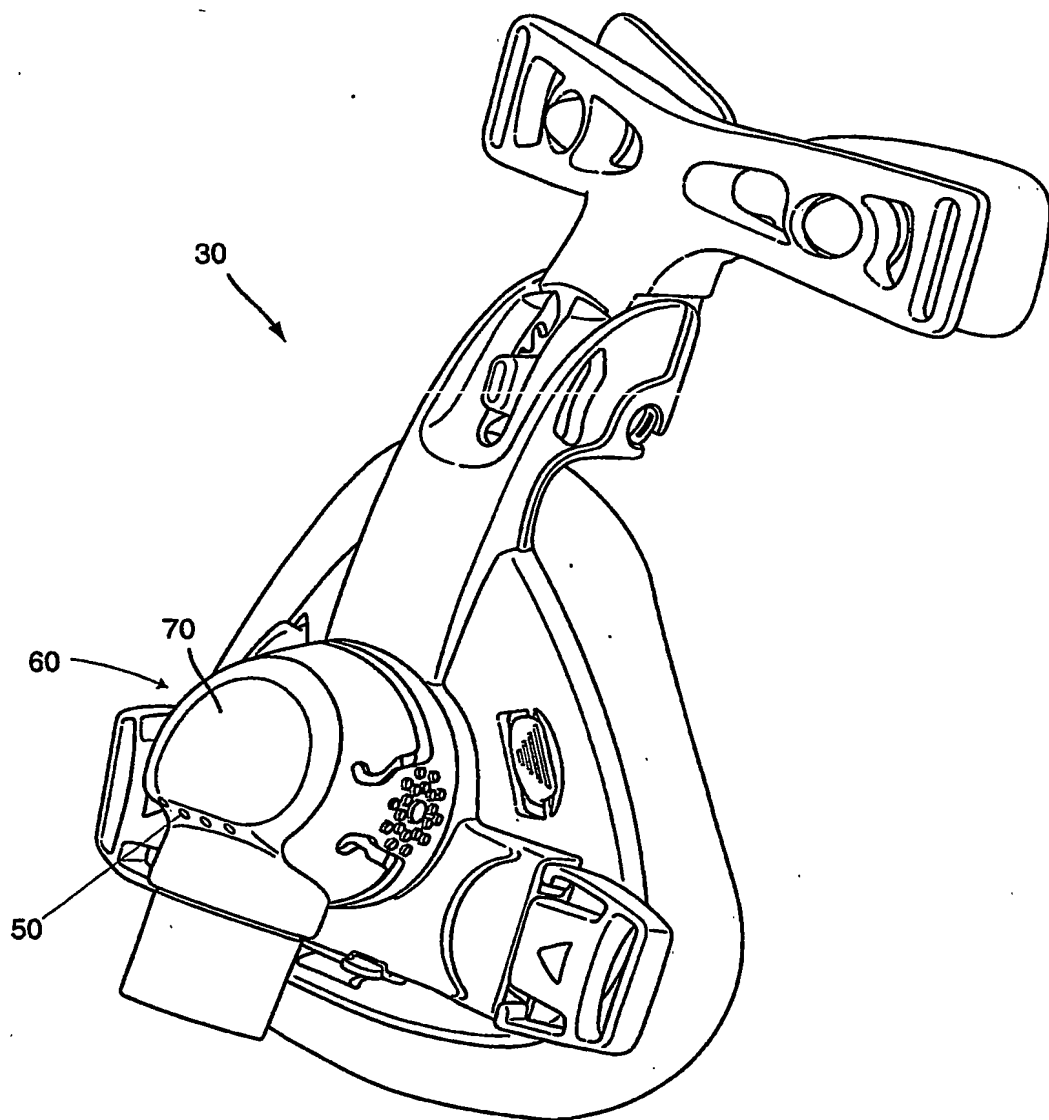


Fig. 2

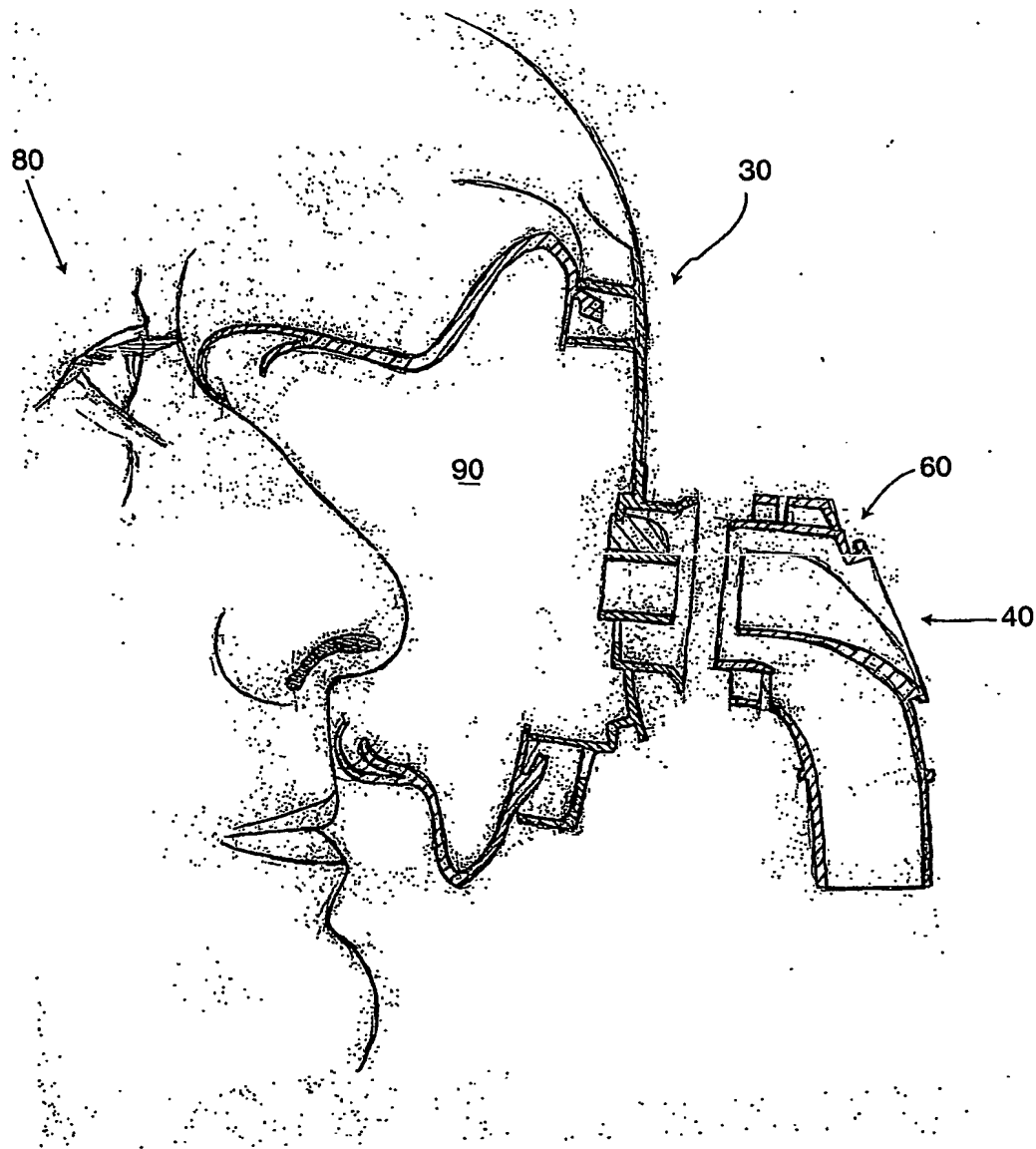


Fig. 3

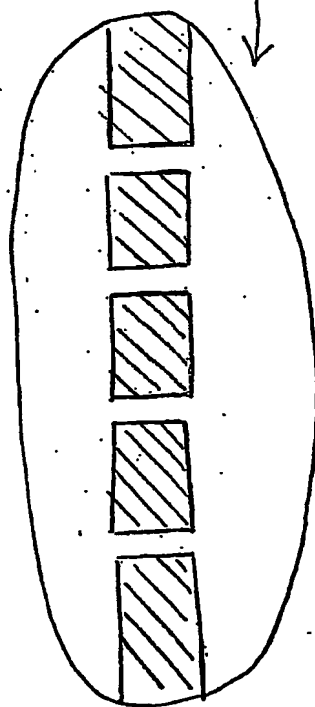
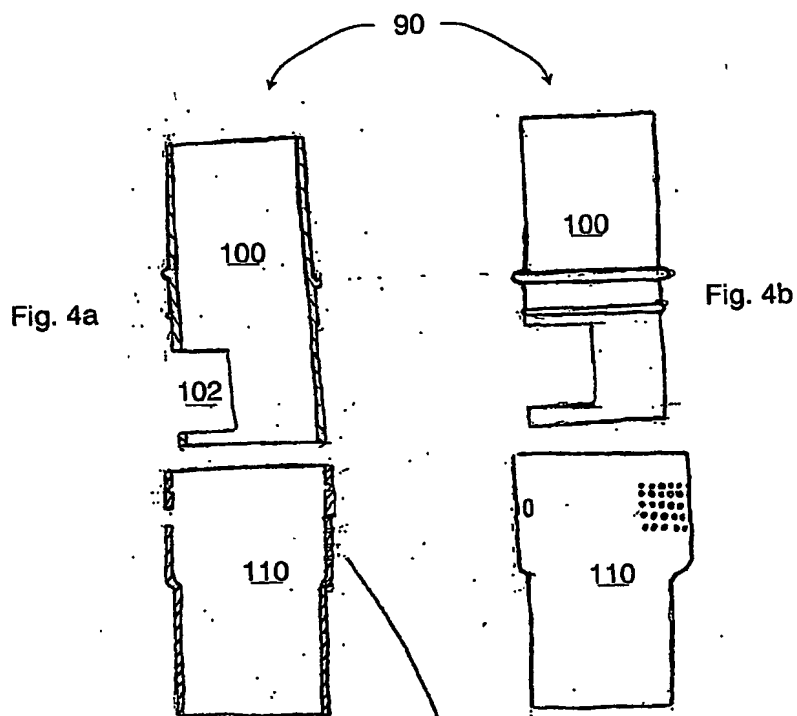


Fig. 4c

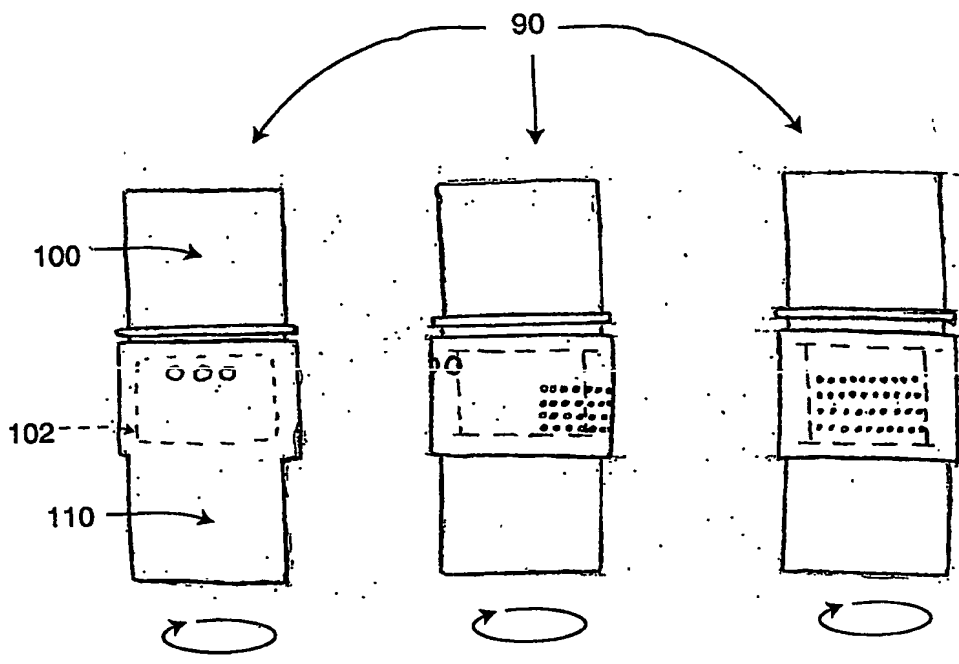


Fig. 5a

Fig. 5b

Fig. 5c

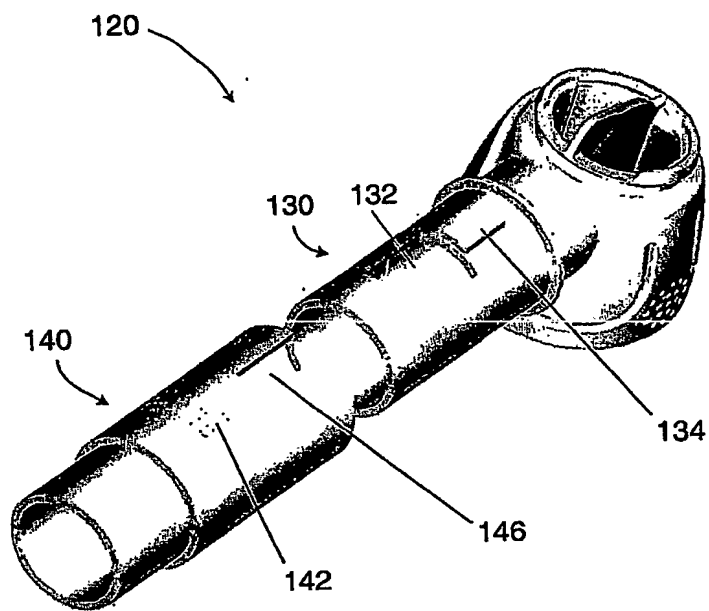


Fig. 6

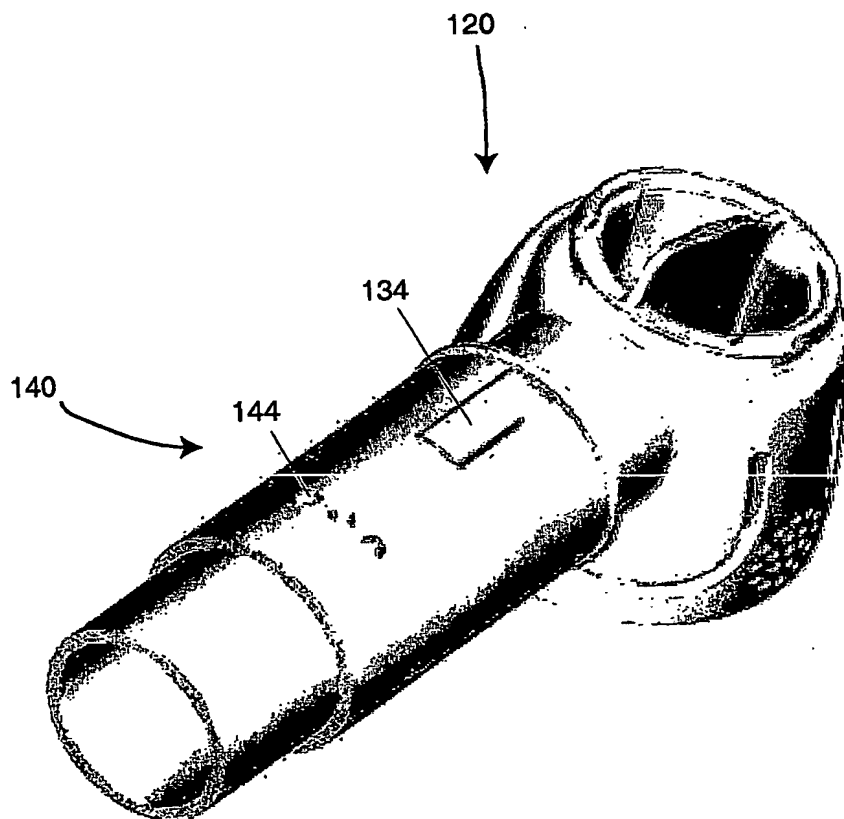


Fig. 7

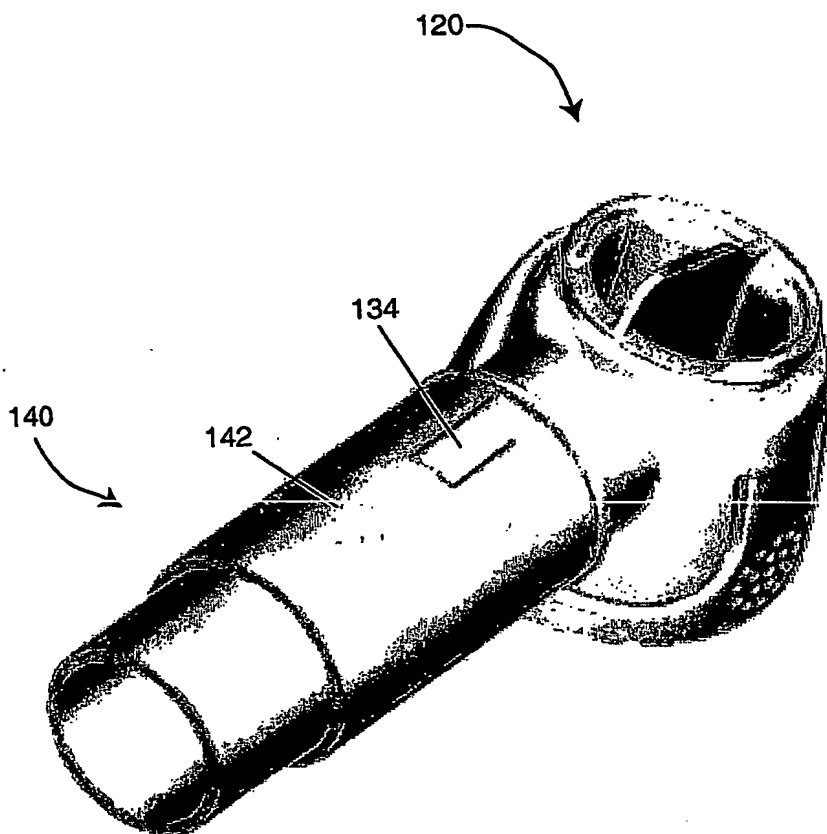


Fig. 8

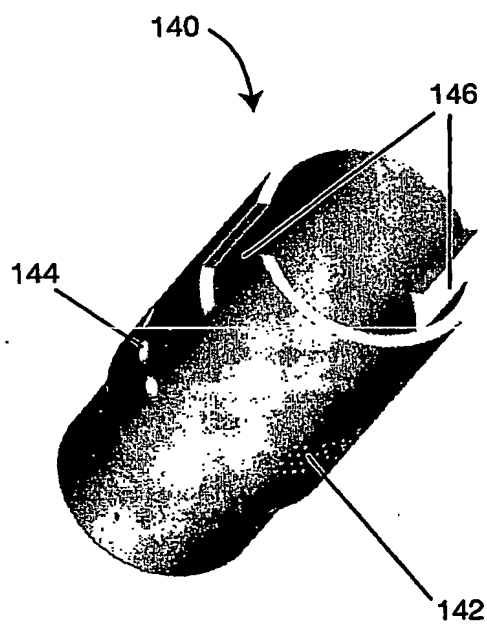


Fig. 9

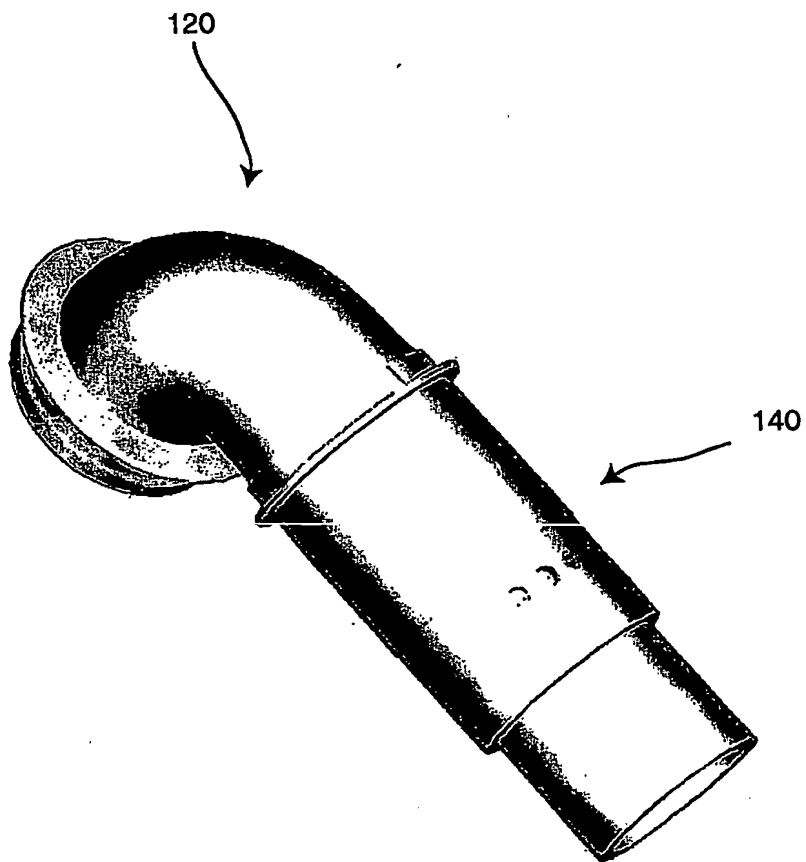


Fig. 10

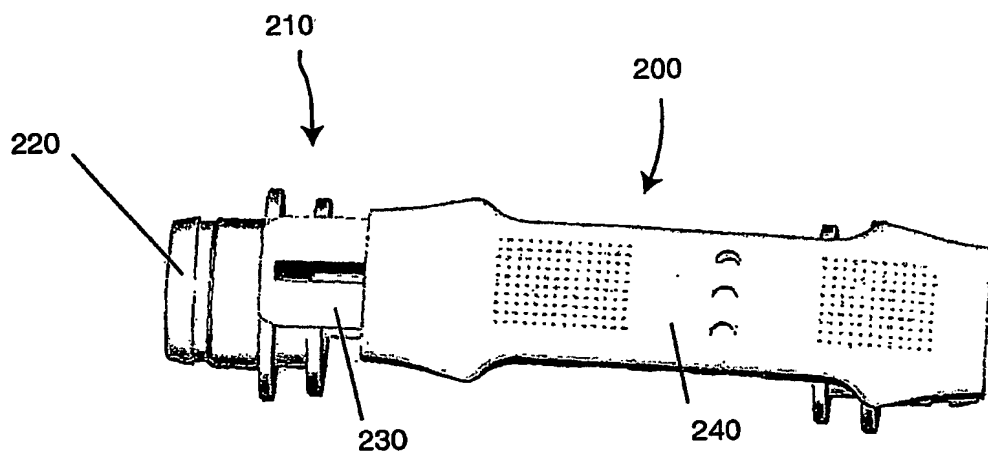


Fig. 11a

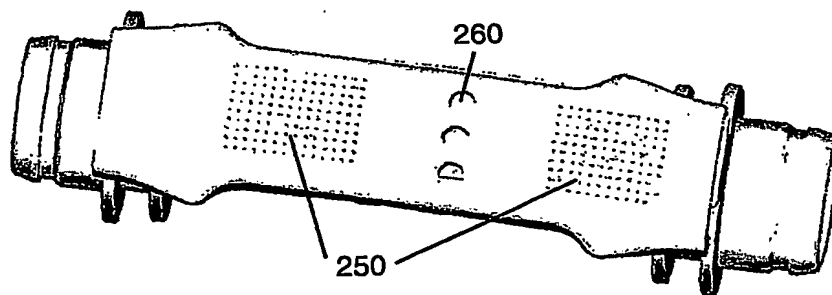


Fig. 11b

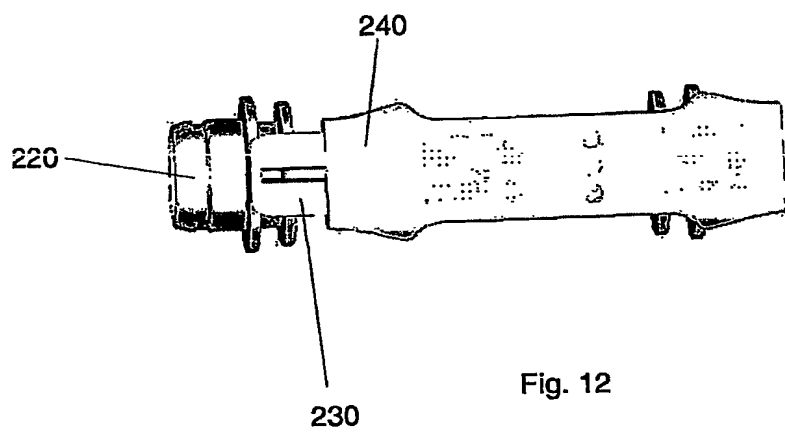


Fig. 12

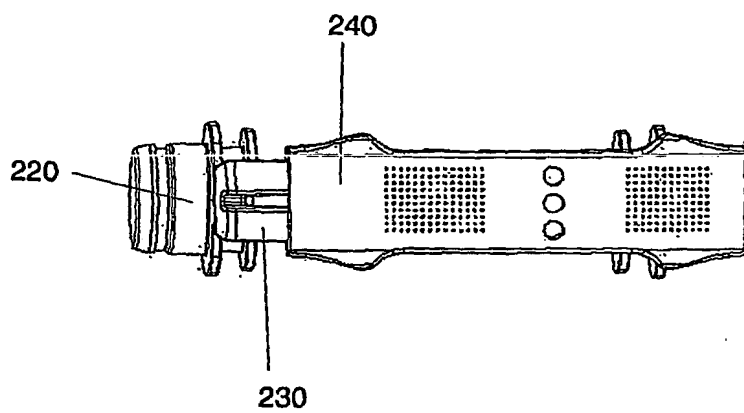


Fig. 13

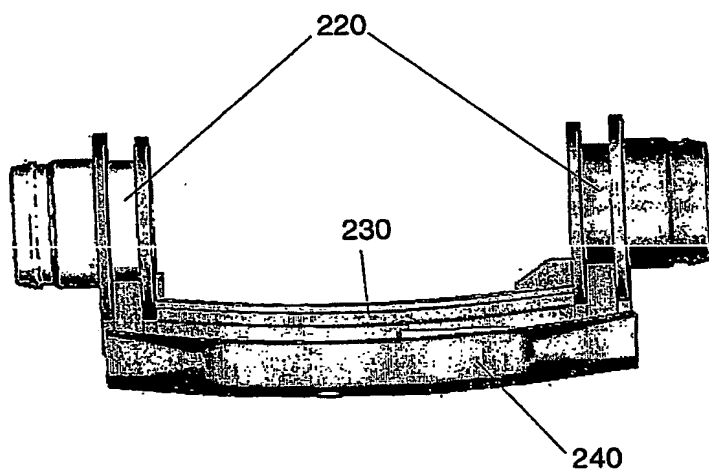


Fig. 14

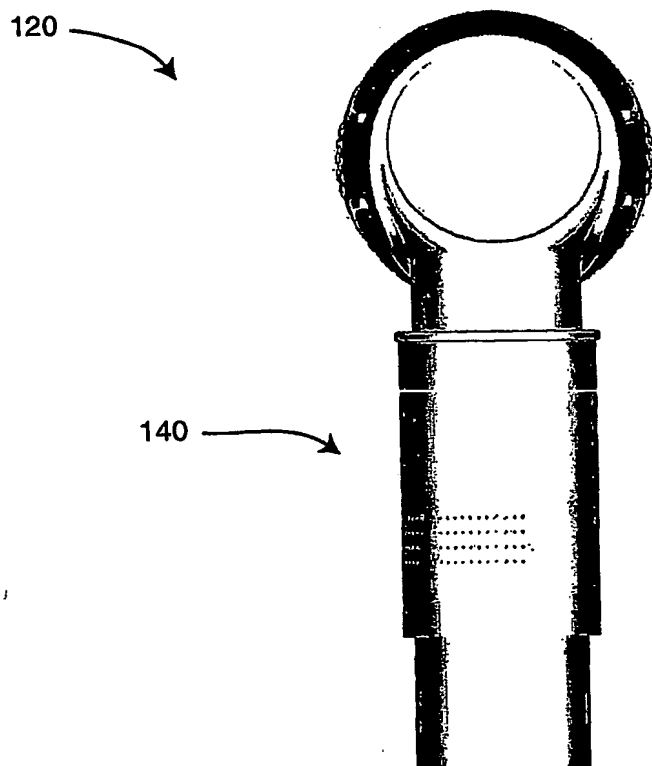


Fig. 15

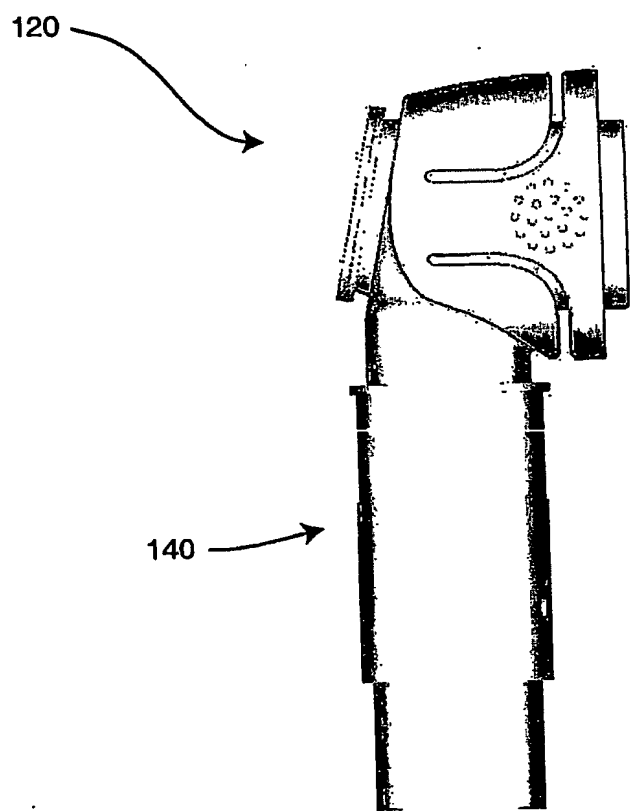


Fig 16

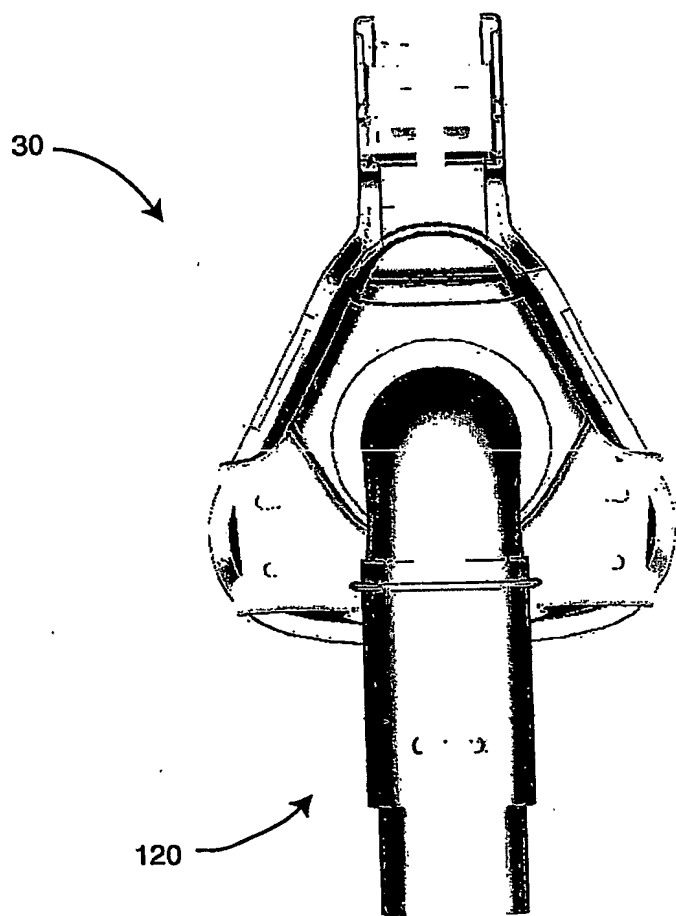


Fig 17

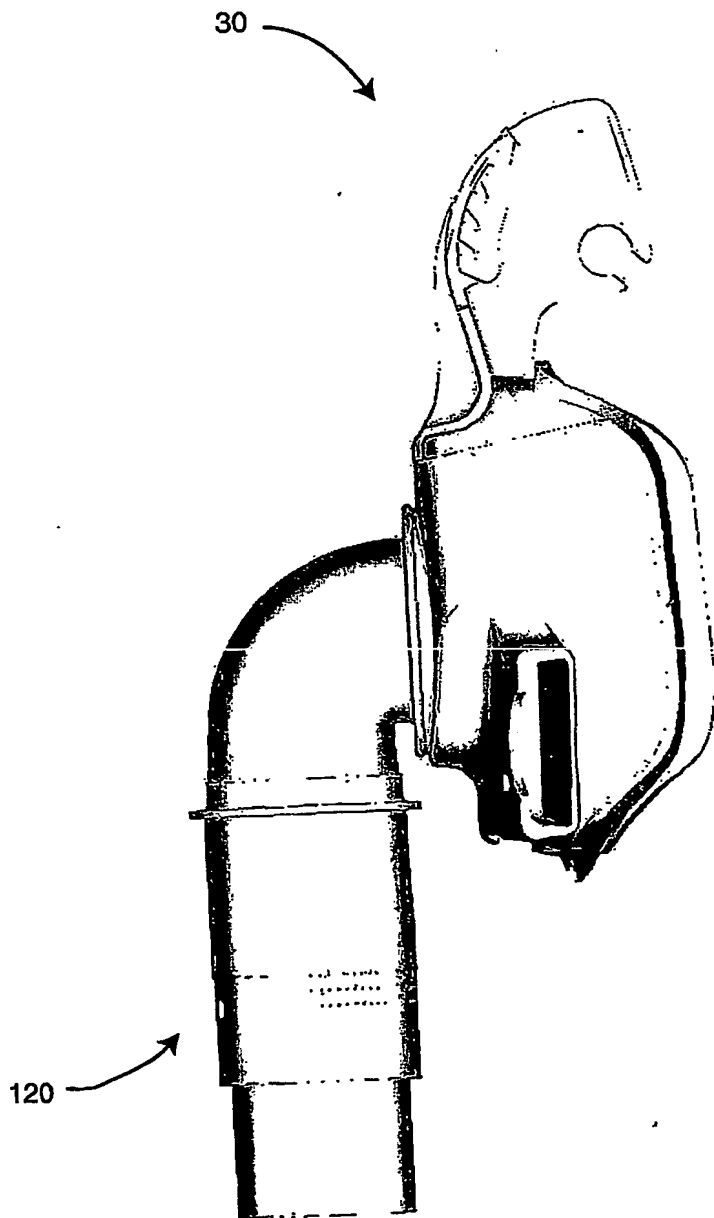


Fig 18

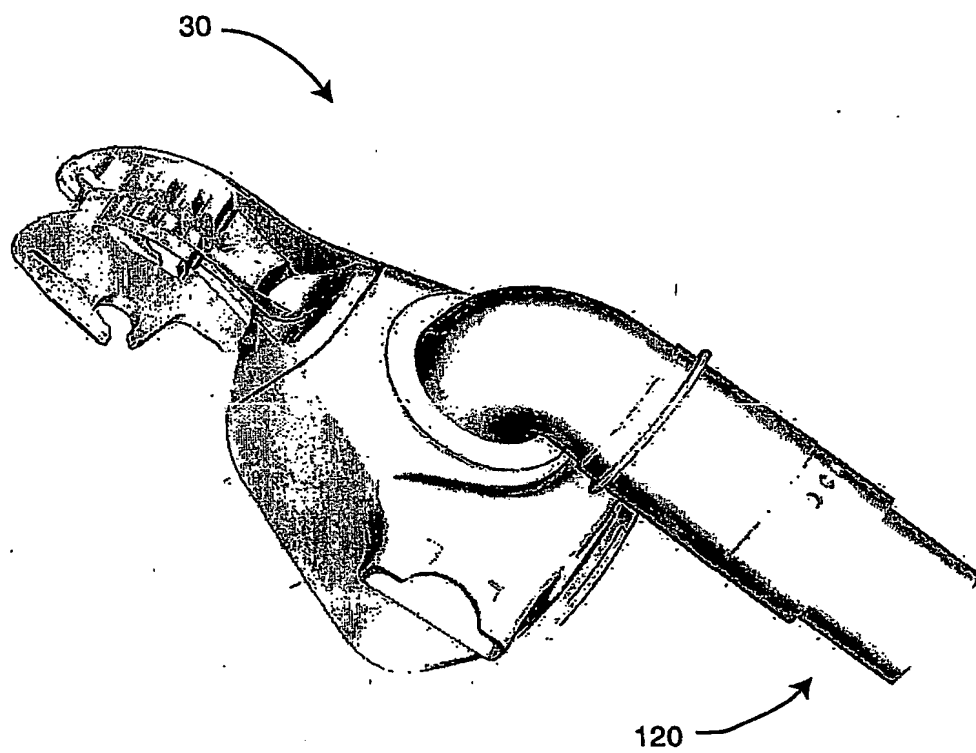


Fig. 19

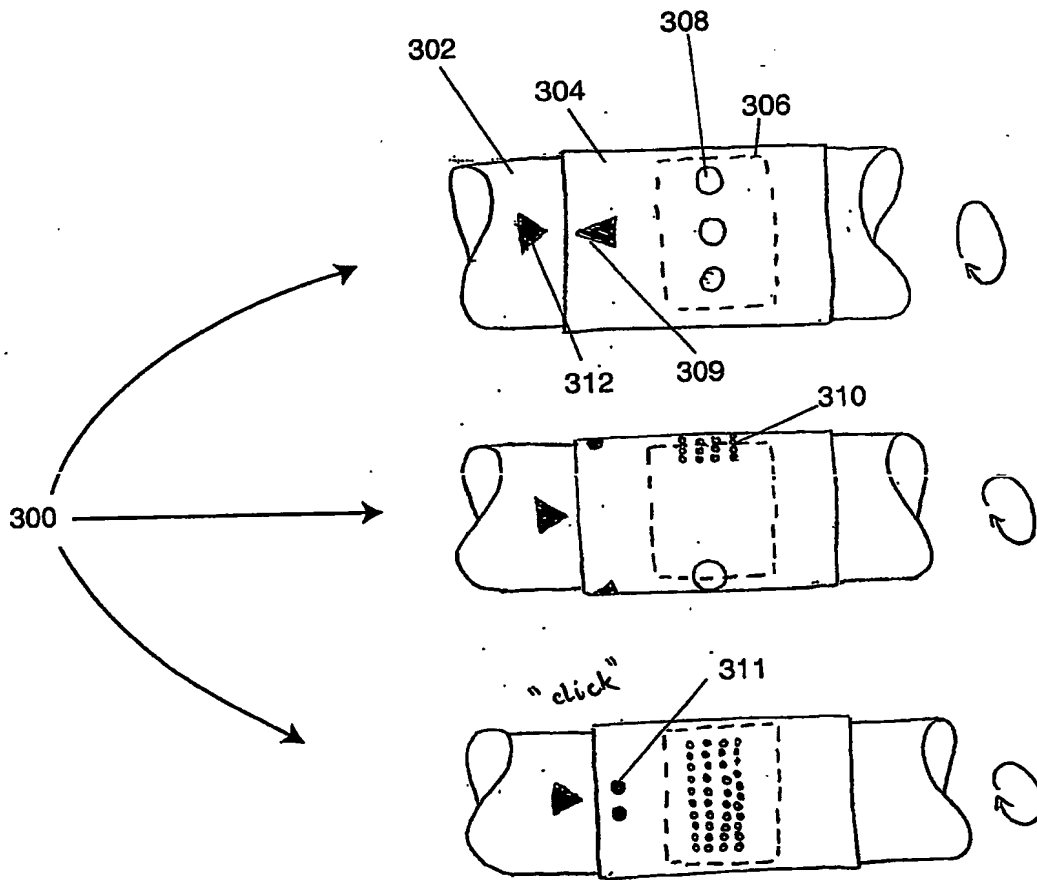


Fig. 20

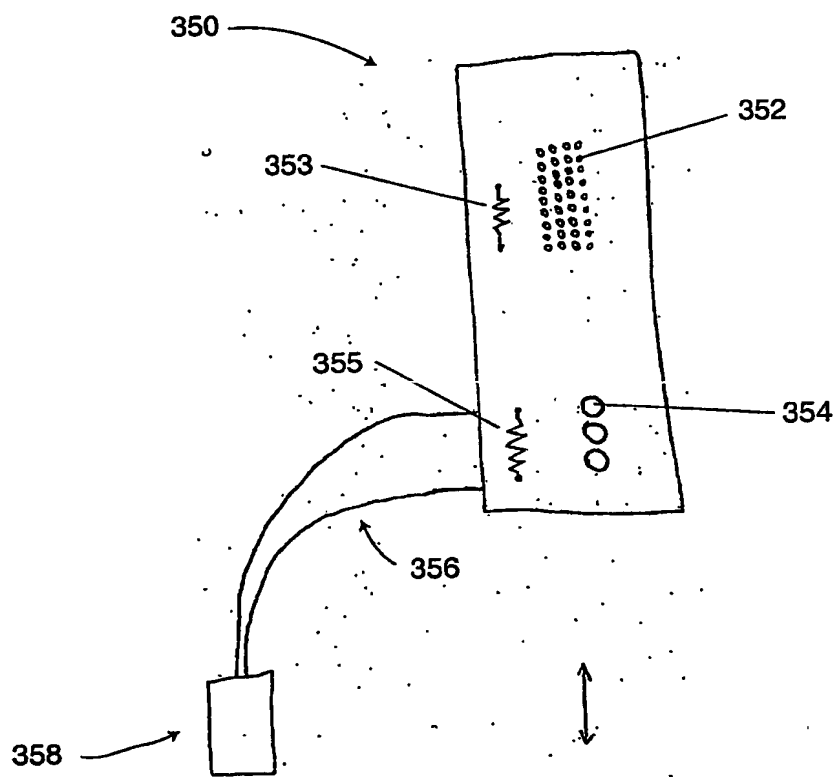


Fig. 21

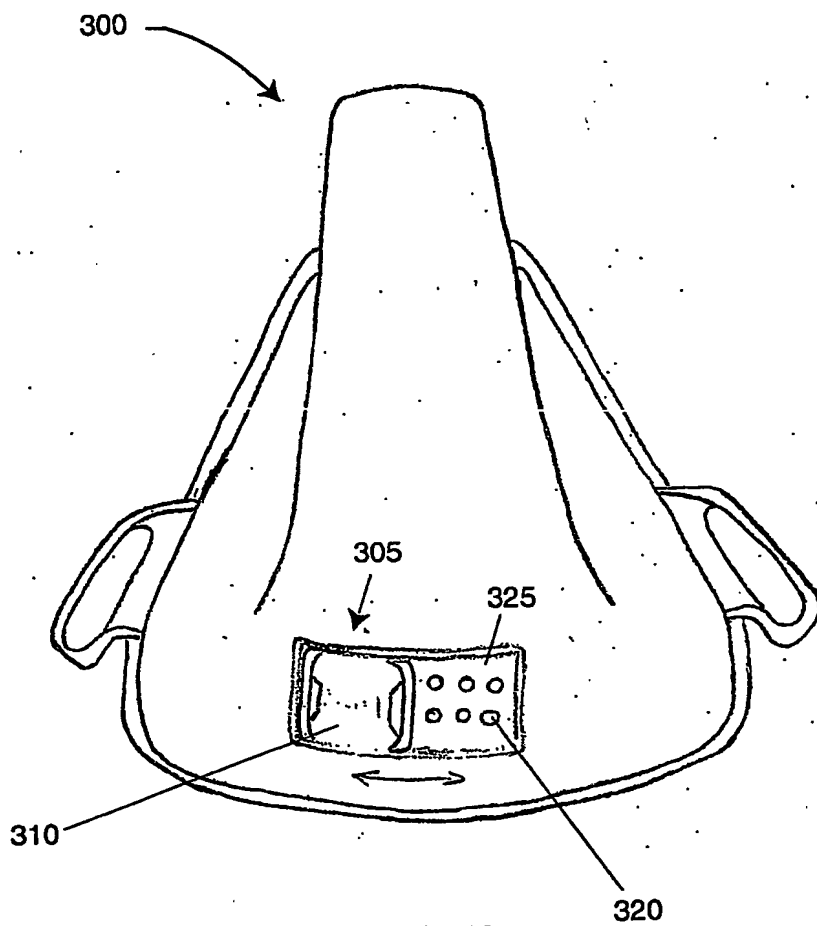


Fig. 22

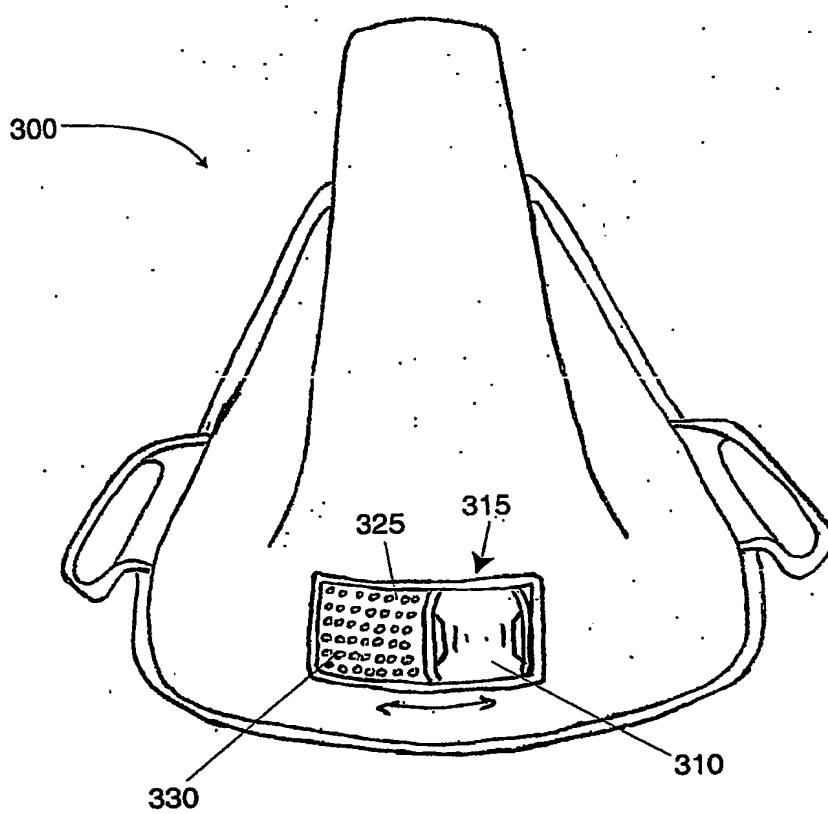


Fig. 23

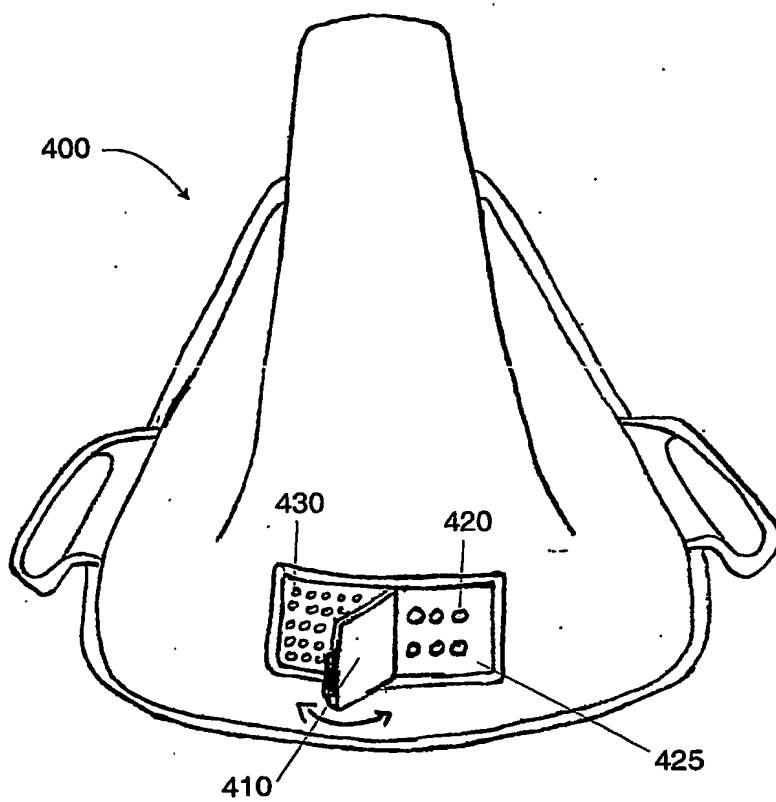


Fig. 24

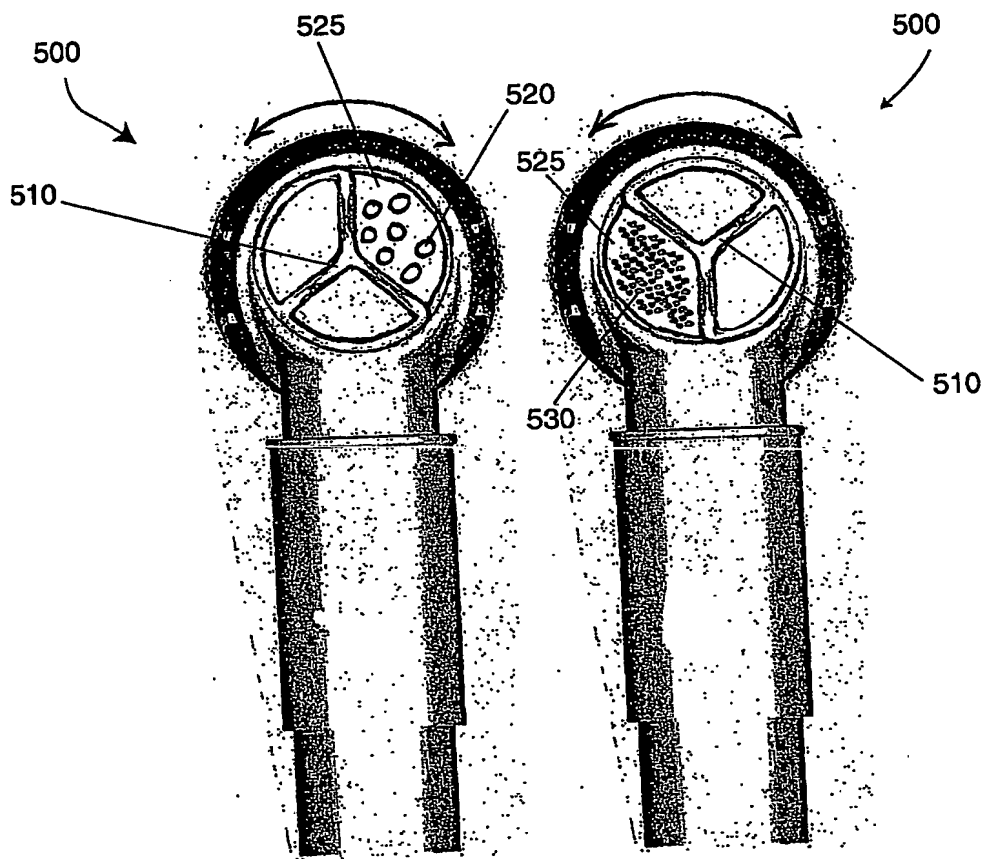


Fig. 25a

Fig. 25b

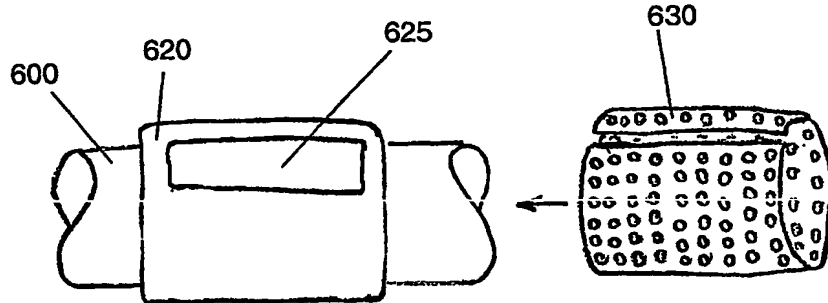
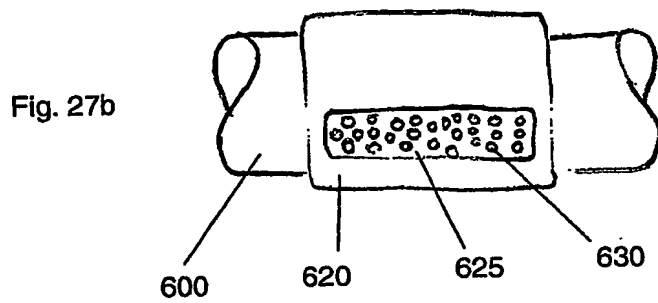
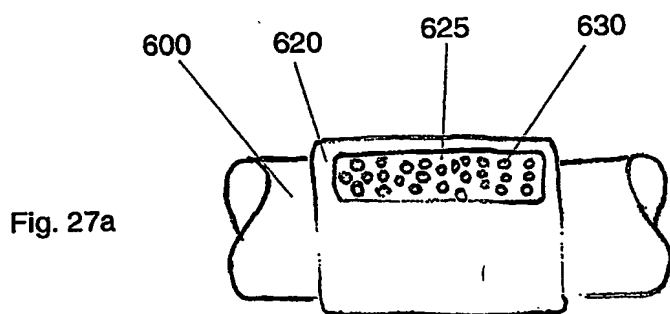


Fig. 26



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